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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/381,344 | 09/20/1999 | GERHARD SEEMANN | 2481.1640 | 3847 |

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| EXAMINER | |
|---|---|
| SGAGIAS, MAGDALENE K | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 12/28/2006 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

| Advisory Action Before the Filing of an Appeal Brief | Application No. 09/381,344 | Applicant(s) SEEMANN ET AL. | |
|---|---|---|---|
| | Examiner Magdalene K. Sgagias | Art Unit 1632 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 06 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *06 November 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *11,12,16-21,23,25-30 and 32*.
   Claim(s) withdrawn from consideration: *19-22*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Continuation of 11. does NOT place the application in condition for allowance because: Applicants have failed to provide evidence to overcome the rejections under 35 USC 112, 1st paragraph, enabelement rejection or the rejections under 35 USC 103 as being unpatentable over Smith and Trapnell. Applicants does not reasonably provide enablement for increasing tolerance in a mammal to transgenic cells produced in vitro and introducing said cell into a mammal and administering an immunosuppressant to increasing the tolerance of the mammal to the trnasgenic cells. Applicants argue that: "For example, in the specification they describe that genetic material is inserted into cells in vitro or in vivo in the form of one or more nucleic acid chains, which is carried out with different vectors by means of transfection. If the genetic material is inserted in vitro as described in the specification, then to get the genetic material into the mammal, an ex vivo method must be employed". Applicants further argue that they have provided publications which show that several ex vivo methods for administering gene therapy were known in the art at the time of the time the application was filed. This is not found persuasive because Applicants have failed to provide a correlation of introducing a transgene into a cell of a mammal ex vivo capable of expressing a transgene, introducing said transgenic cells into said mammal and administering an immunosuppressant resulting in increasing tolerance to transgenic cells.

Applicants also argue that Smith' and Trapnell's object of their invention is to provide sustained efficacy of gene transfer via preferred administration of adenoviral vectors and for sustained expression of the trasferred gene through the suppression of an immune response against the adenoviral vectors, and Applicants further argue claims 16 and 26 distinguish over the disclosure of each of these references in reciting "a single administration of a vector". This is not found persuasive for the reasons stated in the previous office action mailed 7/6/06.

Applicants further argue that in contrast to Smith and Trapnell aplicant's invention is directed to increasing tolerance to the transgenic cells by suppression of the cellular immune response. Though Thomson do not specifically analyze nor demonstrate the suppression of the cellular immune response, clearly they have practiced the method step encompassed by the instant claim, and provide for the cellular immune reposne.